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Peter Charles Summersell

PROVISIONAL SPECIFICATION

Invention Title:

Surgical device

The invention is described in the following statement:

Field of the Invention

The present invention relates to an apparatus for surgically incising a flexor retinaculum of a patient to relieve the symptoms of carpal tunnel syndrome.

Background Art

Carpal tunnel syndrome is a condition wherein one of the nerves of the hand, the median nerve is compromised in some manner. Typically, it presents as a tingling, paraesthesia or uncomfortable feeling in the hand. Other symptoms include weakness of the hand to a degree that prevents manipulation of objects previously easy to handle. The tingling or numbness tends to follow the distribution of the median nerve, that is, it affects the thumb, index, middle and half of the fourth finger although in the early stages, the symptoms may be perceived as being throughout the entire hand.

As the median nerve becomes increasingly damaged, the symptoms may become more severe including complete numbness and increased pain.

In most cases of carpal tunnel syndrome, the median nerve is caused to press against the flexor retinaculum, a ligament which forms a boundary of the carpal tunnel. The carpal tunnel contains a number of tendons and one nerve, the median nerve. Anything that increases the volume in the carpal tunnel will necessarily increase the pressure in the tunnel, causing the median nerve to press against the flexor retinaculum.

Examples of events which cause an increase in the volume of the contents of the carpal tunnel include fractures of the wrist and other traumatic events, hypertrophy of the tendons which pass through the tunnel (either from exercise or a pathological hypertrophy) or synovitis, the inflammation of the synovium surrounding the tendons of the carpal tunnel.

The symptoms of carpal tunnel syndrome may be relieved by a surgical procedure known as carpal tunnel release. This involves the incision of the skin of the palm of the hand to expose the flexor retinaculum. Once in view, the flexor retinaculum is divided to alleviate the pressure in the carpal tunnel. This form of open surgery to the wrist is the conventional procedure although it does have several drawbacks. For instance, because the procedure requires exposure of the flexor retinaculum, an incision of up to 3 inches is required, leaving the patient with an unsightly scar which may be tender not to mention considerable pain resulting from the operation. Furthermore, because a surgeon is required to dissect down towards the

flexor retinaculum, this procedure requires the cutting of all the structures that lie between the flexor retinaculum and the skin. This increases the likelihood of severe damage to surrounding tissues and nerves.

As an alternative to the open surgery procedure, endoscopic surgery has been employed to reduce the size of the incision and thus the associated drawbacks. Early attempts, however led to an increase in damage to the nerves of the wrist including the median nerve due to the fact that the structures of the carpal tunnel could not be viewed to a satisfactory level. Furthermore, typical endoscopic carpal tunnel release devices require two incisions one in the wrist and one in the palm to form an entry and an exit portal.

US 5366465 to Mirza describes a method of dividing the flexor retinaculum of a patient using endoscopic means which requires only one incision in the skin of a patient, that incision being in the palm. The device employed in this invention, however, requires a knife to be positioned upon the end of an endoscope, the knife being employed to cut the flexor retinaculum from the deep aspect towards the superior aspect. This assembly has inherent problems including the lack of constant and unobstructed visualisation of the cutting of the flexor retinaculum including the section of the flexor retinaculum about to be cut. This is critical as often during the insertion of the endoscope, the median nerve will be caused to squash against the endoscope and the flexor retinaculum. The chance of dissection of the median nerve in such cases is high as it is difficult to view the area of the flexor retinaculum about to be cut.

The present invention aims to overcome the above mentioned problems.

Disclosure of the Invention

In a first aspect, the present invention provides a trocar including an elongate body having an open proximal end and an open distal end and a lumen extending therethrough, the body having first and second lipped portions defining a slot, said slot extending longitudinally from a region at least adjacent the proximal end of the body to a region at least adjacent the distal end and wherein the slot is in communication with the lumen of the trocar, the first and second lipped portions of the body extending outwardly from the slot such that when the trocar is inserted into the tissue of an

animal, the lipped portions substantially prevent the entry of an anatomical structure into or over the slot.

In one embodiment, the trocar is adapted for insertion into a carpal tunnel of a wrist of a patient. In this embodiment, the trocar is inserted through the carpal tunnel and posterior a deep aspect of a flexor retinaculum, a ligament which forms a boundary of the carpal tunnel.

In a further embodiment, the lipped portions of the trocar prevent the entry of the median nerve, which passes through the carpal tunnel, into the slot of the trocar.

In another embodiment, one or both of the lipped portions may be made from the material of the remainder of the body or alternatively may be made from a more resiliently flexible material than that of the material of the remainder of the trocar. The advantage of the lipped portions being made from a more resiliently flexible material is clear when it is understood that the flexor retinaculum does not always present a perfectly flat surface or aspect. A resiliently flexible lipped portion of the trocar is capable of following the contours of the surface of the flexor retinaculum thereby enabling the trocar to closely engage the flexor retinaculum.

In a second aspect, the present invention provides an assembly for insertion into a carpal tunnel of a wrist of a patient, the assembly including:

a trocar as defined in the first aspect of the invention;

an obturator adapted for insertion through the lumen of the trocar;

an endoscopic means also adapted for insertion through the lumen of the trocar; and

a cutting device including an elongate handle having a proximal end and a distal end and a cutting means located adjacent the distal end of the cutting device wherein the cutting device further comprises a portion which is adapted for insertion into the slot of the trocar.

In one embodiment of the second aspect of the invention, the elongate handle of the cutting device is angled relative to the longitudinal axis of the cutting device.

In another embodiment, the distal end of the cutting device comprises a hook-like member having an inner and an outer rim. In a preferred embodiment, the inner rim of the hook-like member forms the cutting means.

Alternatively, a separate cutting means may be attached to the inner rim of the hook-like member.

In a further embodiment, the cutting means comprises a blade having a cutting edge suitable for cutting the flexor retinaculum of a patient.

In a still further embodiment, the cutting means may be covered by a removably mounted shielding means. Alternatively, the cutting means may be retractable.

In a still further embodiment, the obturator comprises a body having a tapered leading end. The obturator can also have an upstanding rib portion extending along a substantial length of its body.

In another embodiment, the obturator is adapted for insertion into the slot of the trocar such that the tapered leading end of the obturator extends from the distal end of the trocar and the upstanding rib portion extends through the open slot of the trocar.

In another embodiment, the endoscopic means has a proximal and a distal end wherein the distal end of the endoscopic means is tapered.

In another embodiment, the assembly further comprises a probe for insertion through the carpal tunnel of a patient and superior the superficial aspect of the flexor retinaculum.

In a still further embodiment the assembly further comprises a stabilising means for engagement with the proximal end of the trocar or a region adjacent thereto.

In another embodiment, the stabilising means includes a platform and a clamp.

In a further embodiment, the platform includes a groove for receiving a portion of the trocar.

In a still further embodiment, the clamp comprises a simple boss clamp.

In a third aspect, the present invention provides a method of cutting a flexor retinaculum of a patient comprising the steps of:

inserting an obturator into the trocar defined in the first aspect of the present invention;

making an incision on a patient to establish an entry portal;

inserting the trocar and obturator assembly into the entry portal and through a carpal tunnel of a patient to a point posterior an edge of a deep aspect of the flexor retinaculum distal the incision;

withdrawing the obturator from the trocar;

slidably introducing an endoscopic means into the lumen of the trocar to a point adjacent the distal end of the trocar;

introducing a cutting device having a proximal and a distal end into the incision and guiding said cutting device such that the cutting device is guided anterior a superficial aspect of the flexor retinaculum;

positioning a cutting means located adjacent the distal end of the cutting device beyond a distal edge of the flexor retinaculum such that the cutting means may be viewed by way of the endoscopic means positioned deep to the flexor retinaculum;

moving the endoscopic means towards the proximal end of the trocar;

causing at least a portion of the cutting device to be inserted into the slot at a region adjacent the distal end of the trocar and moving the cutting device towards the proximal end of the trocar such that the cutting means is drawn through the flexor retinaculum thereby dividing the flexor retinaculum.

In a further embodiment, the incision is made on the volar aspect of a wrist of a patient.

In a still further embodiment, a blunt probe is inserted into the incision and towards the flexor retinaculum, the probe acting to free tissue from both the deep and superficial aspects of the flexor retinaculum.

In another embodiment, the trocar and obturator assembly is inserted through the incision and positioned adjacent the deep aspect of the ulnar side of the flexor retinaculum.

In a still further embodiment, the proximal end of the trocar is clamped to a stabilising means positioned on the wrist of a patient. In this embodiment, the stabilising means comprises a platform having a grooved section and a clamp. A portion of the body of the trocar lies within the groove of the platform and a region adjacent the proximal end of the trocar is engaged by the clamp. This has the advantage of stabilising the trocar to prevent unnecessary movement of the trocar once it has been positioned within the carpal tunnel of a patient.

In another embodiment, following removal of the obturator from the trocar and insertion of the endoscopic means, a blunt ended probe is inserted and positioned adjacent the superficial aspect of the flexor retinaculum.

Preferably, the probe is positioned such that the blunt end extends a distance just beyond the distal edge of the flexor retinaculum such that it is viewed by the endoscopic means which is positioned deep to the flexor retinaculum. The visualisation of the probe has the advantage of ensuring that the endoscopic means is so placed so as to view the edge of the flexor retinaculum distal the incision. Accordingly, it can be taken that subsequent positioning of a cutting means in the position of the probe will result in successful cutting of the flexor retinaculum from the edge distal the incision.

In another embodiment, the portion of the cutting device inserted into the slot of the trocar comprises a bulb-like structure which locks into the slot of the trocar thereby securing the cutting device to the trocar. This has the advantage of preventing unnecessary movement of the cutting device during the procedure of cutting the flexor retinaculum and thus ensures a straight cutting path.

In a further embodiment, the endoscopic means is moved towards the proximal end of the trocar to enable insertion of the portion of the cutting device into the slot of the trocar. The endoscopic means may then be moved in a direction both towards the proximal and the distal ends of the trocar such that the entire area anterior the endoscopic means is viewed. In this embodiment, the endoscopic means will view the median nerve should it be caused to enter or lie across the slot of the trocar. Accordingly, this embodiment has the advantage of maintaining an unobstructed view of the cutting means and the cutting of the flexor retinaculum thereby preventing damage to any structures and in particular cutting of or damage to the median nerve.

In a further embodiment, an artificial cutting device without the cutting means but of the same shape and size as the true cutting device may be inserted and positioned anterior the superficial aspect of the flexor retinaculum to ensure that the cutting device is positioned so as to engage the trocar and cut the flexor retinaculum.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawing, in which:

Figure 1 is a perspective view of the first aspect of the invention.

Figure 2 is a side view of one embodiment of the first aspect of the invention with a second aspect also present.

Figure 3 is a cross-sectional view through the wrist of an individual.

Figure 4 is a side elevational view of a further embodiment of the second aspect of the invention.

Figure 5 is a side elevational view of a commonly available endoscope.

Figure 6 is a side elevational view of a further embodiment of the second aspect of the invention.

Figure 7 is a cross-sectional view through I-I of Figure 6.

Figure 8 is a cross-sectional view through II-II of Figure 7.

Figure 9 is a schematic view of a hand and wrist of a patient.

Best Mode of Performing the Invention

In one embodiment of the present invention, there is provided a trocar 10 comprising a body 11 which has a proximal end 12 and a distal end 13. A longitudinal slot 14 extends along the body 11, the slot 14 being flanked along the length of a body by lipped portions 15 of body 11. In Figure 1, the width of the slot 14 is somewhat exaggerated for clarity purposes and it is envisaged that the slot 14 is in fact quite narrow. The shape of the trocar 10, having lipped portions 15, has the advantage of preventing the entry of any anatomical structure into slot 14 of the trocar 10. In particular and in the present case, when the trocar is used in effectuating release of a flexor retinaculum 17 to alleviate the symptoms of carpal tunnel syndrome, the lipped portions 15 prevent the entry of the median nerve 18 into the slot 14. This is critical as ultimately and as described below, the trocar 10 may act as a guide for a knife 24 which is employed to divide the flexor retinaculum 17. If the median nerve 18, which passes through the carpal tunnel 16, slips into the slot 14 of the trocar 10, it may be cut during the procedure leading to the loss of the nerve supply to the thumb, second, middle and half of the fourth finger.

In use during the procedure of cutting the flexor retinaculum 17 of a patient, an obturator 21 is inserted into the trocar 10 such that a distal end 22 of the obturator 21 extends from the distal end 13 of the trocar 10. The extension of the obturator 21 provides a smooth surface at distal end 13 of trocar 10 thus allowing for smooth passage through a carpal tunnel 16 of a patient thus preventing any damage to the surrounding tissue. The obturator 21 is further provided with an upstanding rib portion 20 which extends through and is in close engagement with slot 14 of trocar 10 in which the obturator 21 is inserted. The upstanding rib portion 20 provides a smooth

outer surface to the trocar 10 thereby reducing the likelihood of damage to surrounding tissue when the trocar 10 is inserted into the carpal tunnel 16 and further, preventing the entry of any anatomical structures into slot 14 of trocar 10.

The surgical assembly of the present invention further comprises an endoscope 23 and a knife 24. The endoscope 23 comprises a rod member connected to a video display (not shown). The endoscope also has a tapered or angled leading end 25 comprising the lens, the tapering of the leading end enabling an area superior end 25 to be viewed.

The knife 24 of the assembly comprises an elongate handle 26 having a proximal end 27 and a distal end 28. A blade 29 is provided at distal end 28. In the embodiment of the invention depicted in Figures 7 and 8, the blade 29 is positioned on an angled portion 31 of distal end 28, the angled portion 31 further comprising an anchor 30 for insertion into slot 14 of trocar 10. The blade may be covered by a sheath (not shown) which is readily removable or may be retractable.

In use, an incision is made on the skin of a patient, preferably on the volar aspect of the wrist. The incision is deepened to expose the fascia below which is carefully dissected to avoid any damage to the median nerve. The distal edge 40 (see Figure 9) of the flexor retinaculum 17 is identified and a blunt probe (not shown) extended through the carpal tunnel 16 towards the distal edge 40 of the flexor retinaculum 17. The probe may be used to free tissue from both the deep (posterior) 32 aspect and the superficial (anterior) 33 aspect of the flexor retinaculum 17 thus exposing the fibres of the flexor retinaculum 17. The probe is then removed and the wrist of the patient extended to a degree to allow insertion of the trocar 10 and obturator 21 through the ulnar side 19 of the carpal tunnel 16.

The trocar 10 and obturator 21 are inserted to a point adjacent the deep aspect 32 and slightly beyond the distal edge 40 of the flexor retinaculum 17. The proximal end 12 of trocar 10 may then be connected to a platform and clamp 34 which acts to prevent any movement of the trocar 10 and obturator 21 from the determined position. Once connected to the platform and clamp 34, the obturator 21 is removed from the trocar 10 and the endoscope 23 inserted into the trocar 10. The endoscope 23 is passed along the length of the trocar 10 such that the tapered leading end 25 of the endoscope 23 extends slightly beyond the distal edge 40 of the flexor retinaculum 17.

A further probe with an angled tip (not shown) may then be positioned adjacent the superficial aspect 33 of the flexor retinaculum 17. The probe is positioned such that the angled tip extends slightly beyond the distal edge 40 of the flexor retinaculum and towards the deep aspect 32 of the flexor retinaculum 17. In this position, the angled tip of the probe should just be in the field of view of the endoscope 23 positioned deep to the flexor retinaculum 17. If this is not the case, the positioning of the trocar 10 and endoscope 23 may be adjusted to enable viewing of the angled tip of the probe. This process ensures that the trocar 10 and endoscope 23 are correctly positioned to allow an unobstructed view of the subsequently introduced knife 24. Once satisfied that the trocar 10 and the endoscope 23 are positioned correctly, the proximal end 12 of trocar 10 is then clamped to platform and clamp 34. The endoscope 23 may then be moved along the length of trocar 10 to confirm that the median nerve 18 is not caught within the slot 14 of the trocar 10.

As a next step, the knife 24 is passed superficial to the ulnar side 19 of the flexor retinaculum 17 and positioned adjacent the superficial aspect 33 of the flexor retinaculum 17. The knife 24 is slowly edged distally until it extends slightly beyond the distal edge 40 of the flexor retinaculum 17 and is in view of the endoscope 23. The knife 24 is lowered towards the trocar 10 and manipulated such that the anchor 30 is inserted into slot 14 of trocar 10. This may involve slightly tilting the knife 24 to allow insertion of the anchor 30 into the slot 14 and subsequently re-aligning the knife 24 such that the anchor 30 is secured within slot 14, thereby securing the knife 24 relative to trocar 10.

The handle of the knife 24 may then be manipulated such that the blade 29 is pulled proximally towards the incision. The blade 29 therefore cuts through and divides the flexor retinaculum 17 from the distal edge 40.

At the same time the blade 29 is pulled towards the incision, the endoscope 23 is also pulled back along the length of the trocar 10 and towards the incision. This enables a continuous view of the blade 29 and the cutting of the flexor retinaculum 17.

Upon complete division of the flexor retinaculum 17, the knife 24 is removed followed by removal of the trocar and endoscope. The skin is sutured and a dressing applied.

Dated this twenty second day of July 1999

Peter Charles Summersell
Patent Attorneys for the Applicant:

F B RICE & CO

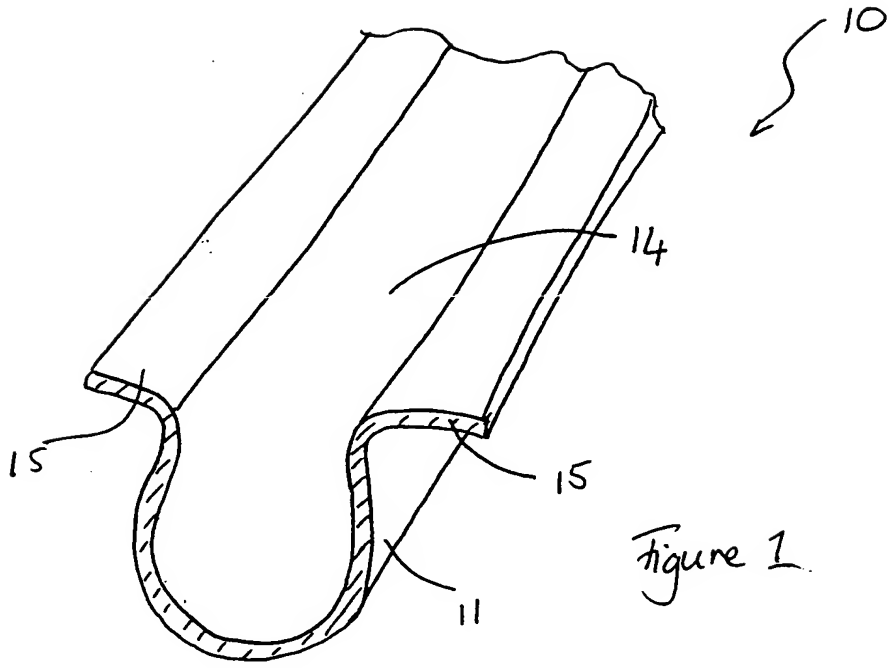


Figure 1

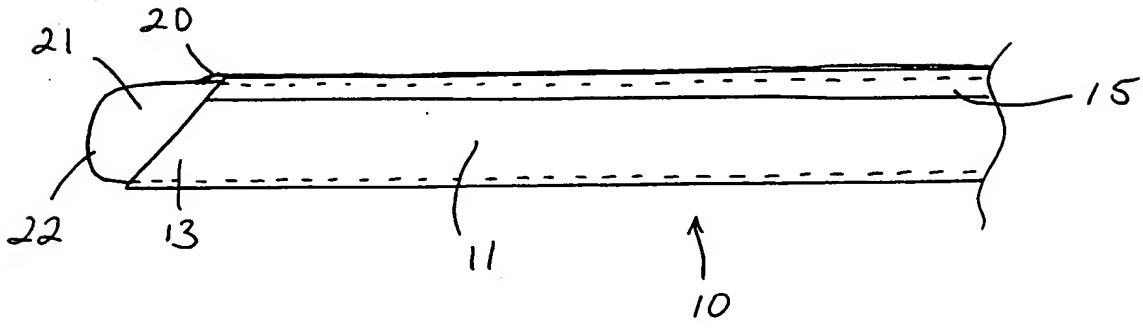


Figure 2.

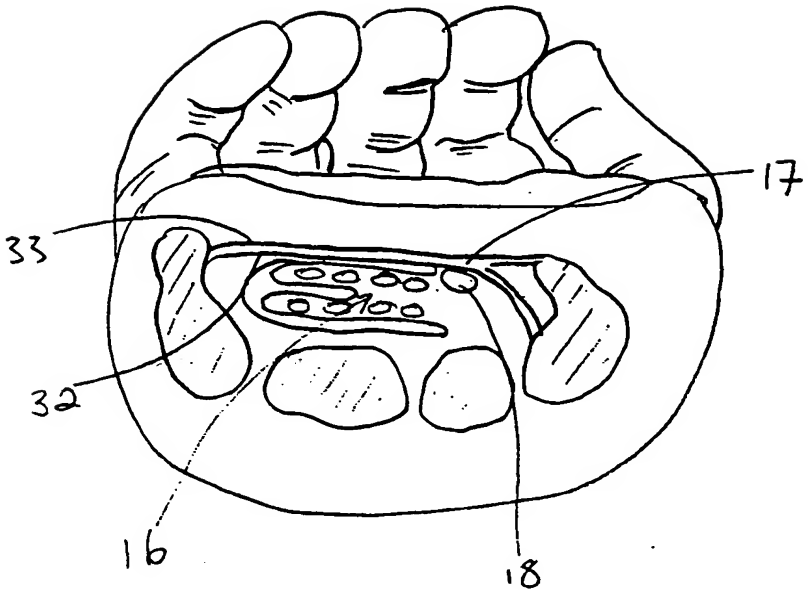


Figure 3

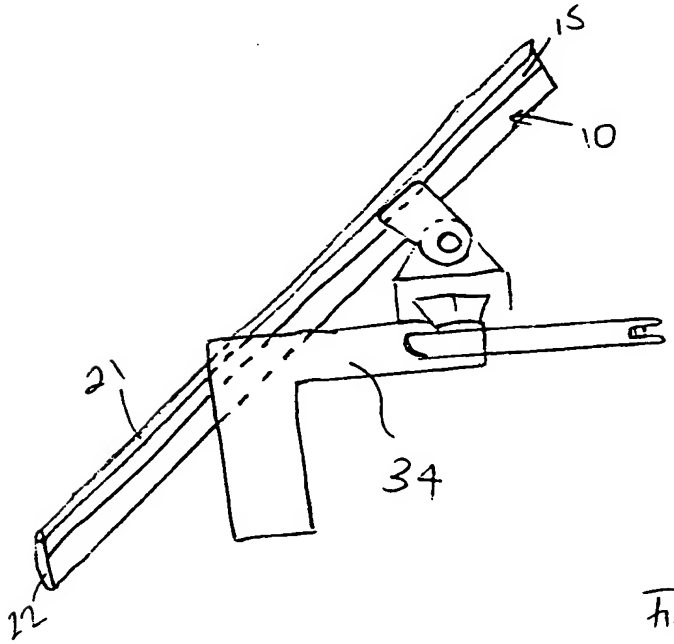


Figure 4

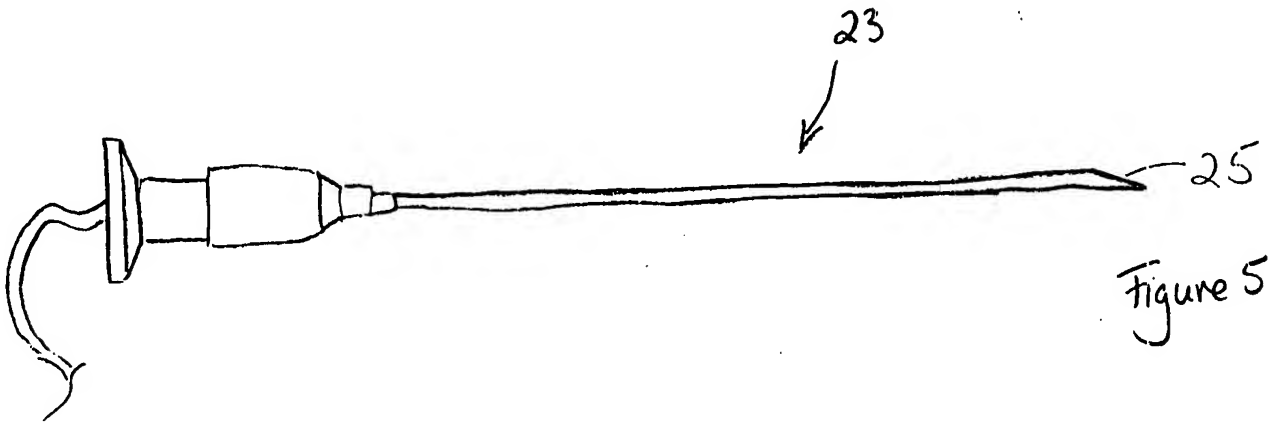


Figure 5

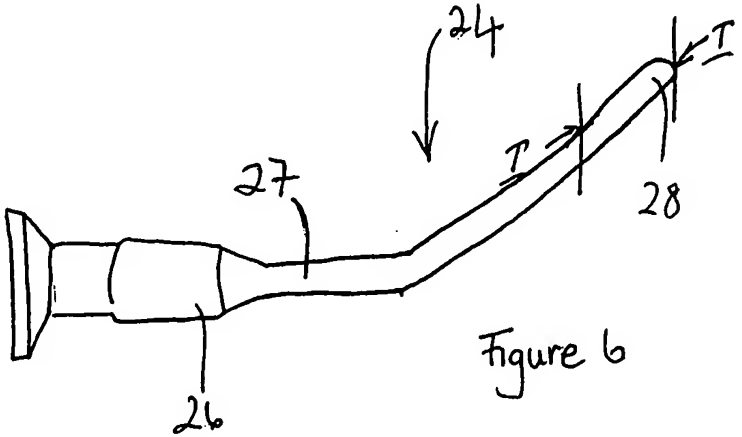
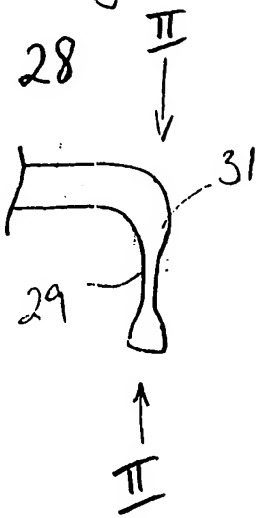


Figure 6

Figure 7



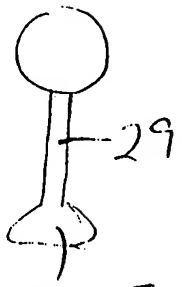


Figure 8

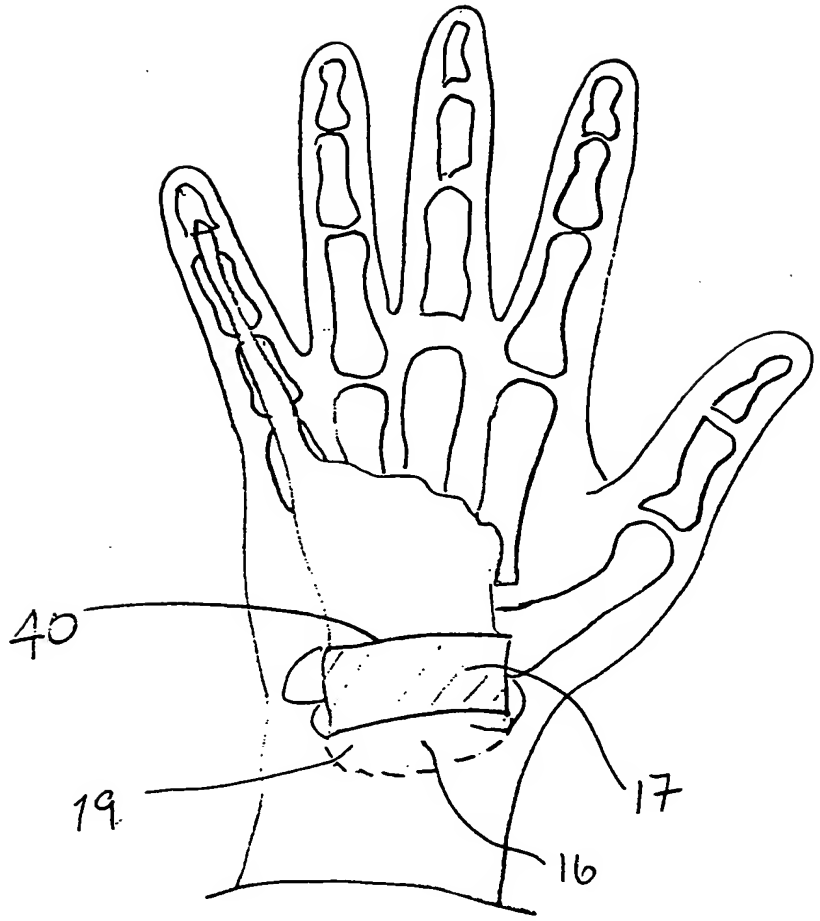


Figure 9